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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,215	03/12/2004	Daniel Rohleder	WP 21723 US	8547
7590	12/11/2006		EXAMINER	
Sujatha Subramaniam Roche Diagnostics Operations, Inc. 9115 Hague Road, Bldg. D Indianapolis, IN 46250			LIN, JACK	
			ART UNIT	PAPER NUMBER
			3768	

DATE MAILED: 12/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/800,215	ROHLEDER ET AL.	
	Examiner	Art Unit	
	Jack Lin	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,2 and 4-31 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) 1,2 and 4-31 is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 12 March 2004 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. This action is in response to applicant's amendments filed on November 21, 2006.
2. The objections to claims 1 and 7 are withdrawn in view of the amendments to the claims.
3. The rejections of claims 5, 8, 12, and 20 under 35 U.S.C. 112, second paragraph are withdrawn in view of the amendments to the claims.
4. The rejections of claims 1-20 under 35 U.S.C. 101 are withdrawn in view of the amendment to claim 1.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

6. Claims 9 is objected to because of the following informalities: It appears claim 9 is trying to further limit the "detection light guide" of claim 1 to a "detection light guide ring which surrounds a central inbound light guide". However, as written, claim 9 requires "a detection light guide ring" in addition to the "detection light guide" of claim 1. Appropriate correction is required.

Claim Rejections - 35 USC § 101

7. Claims 25-31 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. These claims were examined in accordance with the guidelines for statutory subject matter published 22 November 2005 at 1300 OG 142.

Claim 25 specifies a method to determine the concentration of an analyte. However, Claim 25 does not result in a physical transformation nor does it appear to provide a useful, concrete and tangible result. Specifically, it does not appear to produce a tangible result because merely determining the concentration of an analyte is nothing more than a computation within a processor. It fails to use or make available for use the result of the determination to enable its functionality and usefulness to be realized. Additionally, the asserted practical application in the specification of the method to determine the concentration of an analyte is for displaying the result to the user. The practical application is not explicitly recited in the claim nor does it flow inherently therefrom. Therefore, claim 25 appears non-statutory.

Claims 26-31 further limit claim 25 but also do not specifically or inherently produce tangible results from the method steps.

Claim Rejections - 35 USC § 103

8. Claims 1, 2, 4, 5, 9, 10, 20, 23, 24, 25, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ward et al. (International Application WO 02/07585 A2) in view of Ham et al. (US Patent 5,553,616). Ward et al. discloses the invention substantially as claimed including a device and a method of using the device comprising a light source (page 22, lines 11-12), a fiber optic probe that can be inserted into a tissue bed which inherently contains interstitial fluid (page 19, lines 15-16), a charge couple device (page 22, lines 12-13), and a signal analyzer (page 23, line 25) used to produce Raman spectroscopy results (page 25, line 12) of analytes including glucose (page 25, line 17). Ward et al. does not disclose the primary light having a wavelength of at least 550 nm and at most 900 nm. While Ward et al. discloses that one preferred embodiment of the invention is resonance Raman spectroscopy at 390 nm to 420 nm

wavelength (page 15, lines 17-19), Ward et al. also discloses other forms of Raman spectroscopy with other wavelengths may be used (page 15, lines 19-30). Ham et al. teaches using a primary light having a wavelength of 780 nm (column 11, lines 11-13) to produce Raman spectroscopy results of glucose (column 15, lines 34-40 and table 1) since glucose has a rich Raman spectrum when irradiated with a 780 nm monochromatic light (column 15, lines 3-10). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus and method of Ward et al. with a primary light having a wavelength of 780 nm since Ward et al. disclose that their arrangement is suitable for measuring glucose and Ham et al. teach glucose has a rich Raman spectrum when irradiated with a 780 nm monochromatic light.

Regarding Claims 9 and 10, Ward et al. discloses probe of a fiber optic bundle configured with one emitting fiber in the center surrounded by collection fibers (page 22, lines 22-23).

Regarding Claim 20, 24, and 25, Ward et al. discloses the probe to be less than 0.2 mm (page 23, line 4).

9. Claims 1 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ward et al. in view of Chaiken et al. (US Patent 6,377,828). Ward et al. discloses the invention substantially as claimed including a device and a method of using the device comprising a light source (page 22, lines 11-12), a fiber optic probe that can be inserted into a tissue bed which inherently contains interstitial fluid (page 19, lines 15-16), a charge couple device (page 22, lines 12-13), and a signal analyzer (page 23, line 25) used to produce Raman spectroscopy results (page 25, line 12) of analytes including glucose (page 25, line 17). Ward et al. does not disclose the primary light having a wavelength of at least 550 nm and at most 600 nm. While Ward et al. discloses that one preferred embodiment of the invention is resonance Raman spectroscopy at

390 nm to 420 nm wavelength (page 15, lines 17-19), Ward et al. also discloses other forms of Raman spectroscopy with other wavelengths may be used (page 15, lines 19-30). Chaiken et al. teaches using a primary light having a wavelength of 588 nm (column 7, lines 15) to produce Raman spectroscopy results of a temperature probe such as hemoglobin in order to determine the concentration of glucose (column 5, lines 7-27). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Ward et al. with a primary light having a wavelength of 588 nm as taught by Chaiken et al. since Ward et al. disclose that their arrangement is suitable for measuring glucose and Chaiken et al. teaches using a primary light having a wavelength of 588 nm will produce Raman effect in hemoglobin which can be used to determine the concentration of glucose.

10. Claims 25 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ward et al. in view of Yang et al. (US Patent 6,167,290). Ward et al. discloses the invention substantially as claimed including inserting a sensor head (page 19, lines 13-16), shining a monochromatic primary light (page 22, lines 18-21), receiving secondary light (page 22, line 31 – page 23, line 1), detecting Raman scattered components of the secondary light (page 23, lines 14-19), and determining the concentration of an analyte (page 21, lines 27-29). Ward et al. does not disclose the primary light having a wavelength of at between 550 nm and 750 nm. While Ward et al. discloses that one preferred embodiment of the invention is resonance Raman spectroscopy at 390 nm to 420 nm wavelength (page 15, lines 17-19), Ward et al. also discloses other forms of Raman spectroscopy with other wavelengths may be used (page 15, lines 19-30). Yang et al. teaches using a primary light having a wavelength of 632.8 nm (column 5, line 49) to produce Raman spectroscopy results of glucose (column 5, lines 53-56). Therefore, it would have been

obvious to one of ordinary skill in the art at the time of the invention to modify the method of Ward et al. with a primary light having a wavelength of 632.8 nm as taught by Yang et al. since Ward et al. disclose that their arrangement is suitable for measuring glucose and Yang et al. teaches glucose has a Raman signature at 632.8 nm.

11. Claims 6 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ward et al. in view of Ham et al. as applied to claims 1 and 25 above, and further in view of Caro (US Patent 5,348,003). Ward et al. in view of Ham et al. discloses the invention substantially as claimed including a device and method for determining the concentration of an analyte. Ward et al. in view of Ham et al. does not show using a multivariate analysis method for determining the concentration of the analyte from a Raman spectrum. However, Caro discloses a computer that uses a variety of algorithms including multivariate analysis techniques (column 14, lines 3-9) to determine the concentration of glucose (column 4, line 41) from a Raman spectrum (column 9, line 66). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to have provided the analyte concentration determining device and method of Ward et al. in view of Ham et al. with a processor that uses multivariate analysis techniques to determine the concentration of glucose from a Raman spectrum as taught by Caro since Ward et al. in view of Ham et al. teaches using a computing arrangement and Caro teaches one known arrangement suitable for use with the device of Ward et al. in view of Ham et al.

12. Claims 7, 8, 22, 26, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ward et al. in view of Ham et al. as applied to claims 1 and 25 above, and further in view of Haar et al. (PCT Application WO 99/07277) which corresponds to Haar et al. (US Patent 6,584,335 B1). This office action refers to the US Patent for the purpose of referencing the prior

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art but uses the PCT application publication date. Ward et al. in view of Ham et al. discloses the invention substantially as claimed including a device and method for determining the concentration of an analyte. Ward et al. in view of Ham et al. does not show enclosing the sensor head with a semipermeable membrane. However, Haar et al. teaches enclosing a fiber optic probe with a semipermeable membrane (column 5, line 27-30) that has a cut off of 1000 Da (column 5, line 33) in order to avoid protein deposits on the light guide and other interfering effects associated with large molecules in the interstitial liquid (column 5, lines 39-41). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to have provided the analyte concentration determining device and method of Ward et al. in view of Ham et al. with a semipermeable membrane covering the fiber optic probe as taught by Haar et al. in order to avoid the interfering effects associated with large molecules in the interstitial liquid.

Regarding claim 28, Ward et al. discloses analytes that are non-fluorescing and have a molecular weight of at most 50 kDa (page 25, lines 11-25).

13. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ward et al. in view of Ham et al. as applied to Claim 9 above, and further in view of Bernsee (US Patent 3,966,300). Ward et al. in view of Ham et al. discloses the invention substantially as claimed including a device for determining the concentration of an analyte. Ward et al. in view of Ham et al. teaches an arrangement that includes an emitting fiber surrounded by collection fibers but does not show forming a detection light guide ring from a fiber optic tube. However, Bernsee teaches enclosing a fiber optic with a fiber optic sheath (figure 2). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to have provided the

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analyte concentration determining device of Ward et al. in view of Ham et al. with a detection light guide ring formed from a fiber optic sheath as taught by Bernsee since it has generally been held to be within the skill level of the art to modify a device with alternate equivalent expedients.

14. Claims 12-19 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ward et al. in view of Ham et al. as applied to claims 1 and 25 above, and further in view of Wach et al. (US Patent 6,370,406 B1). Ward et al. in view of Ham et al. discloses the invention substantially as claimed including a device and method for determining the concentration of an analyte. Ward et al. in view of Ham et al. only shows the details of one configuration of the fiber optic probe but teaches other configurations may be used (page 22, lines 23-30). Wach et al. discloses a fiber optic bundle with a pencil-point tip having a 40 degree angle (column 29, lines 15-16, figure 27A) with the end faces coated with internally reflective metallic film (column 29, lines 21-22) resulting in a probe with excellent performance for Raman spectroscopy (column 29, lines 15-16). Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to have provided the analyte concentration determining device and method of Ward et al. in view of Ham et al. with the fiber optic probe configurations as taught by Wach et al. in order to have light management with excellent performance for Raman spectroscopy.

Regarding Claims 16, Wach et al. discloses another embodiment with an end-piece that is conically shaped and has a central recess (figure 41).

Regarding Claims 17-19, Wach et al. discloses another embodiment with an end-piece that is separated from the center fiber (column 38, lines 10-11 and figure 40A) thus forming a reflecting sleeve. Wach et al. also discloses having an angle of 10 degrees (column 29, line 19).

Response to Arguments

15. Applicant's arguments with respect to claim 1 have been considered but are moot in view of the new ground(s) of rejection.
16. Applicant does not address the rejections of the dependant claims. It is assumed that applicant's arguments for the dependant claims is the allowability of claim 1. This argument is addressed with regards to the claim 1 above.
17. Applicant also stated an argument with respect to claim 7 which was originally rejected under 35 U.S.C. 103(a) as being unpatentable over Ward et al. in view of Haar et al. Due to applicant's amendment, claim 7 is now rejected under 35 U.S.C. 103(a) as being unpatentable over Ward et al. in view of Ham et al. and further in view of Haar et al. However, since applicant's argument with regards to claim 7 still applies to the new grounds of rejection, applicant's argument will be addressed. Applicant's arguments to claim 7 have been fully considered but they are not persuasive. Applicant argues that the cited prior art does not teach that a semipermeable membrane would be helpful or useful in the context of Raman spectroscopy. Applicant further argues that the semipermeable membrane of the current application is used to reduce significant fluorescence interference. While Haar et al. does not teach the semipermeable membrane would be helpful in the context of Raman spectroscopy, Haar et al. does teach that the semipermeable membrane would be useful for analysis devices having a measuring probe that pierces through the skin (column 1, lines 3-6). One such device is the device disclosed by Ward et al. in view of Ham et al. Thus, there is proper motivation to combine the teachings of Haar et al. with the device disclosed by Ward et al. in view of Ham et

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al. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jack Lin whose telephone number is (571) 272-7694. The examiner can normally be reached on Monday-Friday, 8:00 a.m. - 4:30 p.m. EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on (571) 272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JL
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ERIC F. WINAKUR
PRIMARY EXAMINER

